



State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | <http://www.pharmacy.ohio.gov>

License 020140500
Cvs/pharmacy #3326

9040 Mentor Avenue
Mentor, OH 44060
Lake County

Retail Pharmacy-Large Chain
Category Three
Standard Retail Pharmacy Inspection Version 1.0

August 31, 2016

Written Response Required

Written Response Required Details

1.2) The Responsible Person

- 2) Have changes in the pharmacy's "Responsible Person" been properly reported to the OSBP?

3.6) Other Areas Requiring Positive ID

- 4) Is there positive ID for patient counseling?

6) Security

- 3) Are all records of accountability that are stored outside of the pharmacy barricade but within the same physical loca...

22) Drug Labels

- 1) Are the pharmacy prescription labels in compliance with OAC 4729-5-16?

28) Rx's Initialed & Dated

- 1) Are pharmacists initialing and dating prescriptions when required?



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Full

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Completed by William Trey Edwards

Start 8/31/2016 1:45 PM

End 8/31/2016 4:15 PM

Organization

Name

Cvs/pharmacy #3326

License Type

Retail Pharmacy-Large Chain

Category

Category Three

License Number

020140500

Business Type

Large Chain Pharmacy - 12 or More Outlets

DEA Number

AR7232781

Responsible Person

Sarah Marie Faetanini, RPH

Hours of Operation

M-F 8a90p Sat 9a-6p, Sun 10a-6p

Contact

Address

9040 Mentor Avenue
 Mentor, OH 44060
 Lake County

Primary Number

(440) 255-9159

Fax Number

(440) 255-2400

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Sarah Marie Faetanini, RPH		Pharmacist	03233512	Redacted	
Christy Marie Peacock, RPH		Pharmacist	03227631		

1.1) The OSBP License

1) Is the pharmacy TDDD license readily retrievable for inspection?

Yes

2) Is the Pharmacy TDDD license current and up to date?

Yes

Observation

The license in the pharmacy lists Daniel Paul Blore, R.Ph. as the responsible person. Sarah Faetanini, R.Ph. states she took over as responsible person in January 2016 so she crossed out R.Ph. Blore's name and signed her name in the presence of Agent Edwards.

3) Has the pharmacy TDDD license been signed by the Responsible Pharmacist?

Yes

Observation

License was signed by R.Ph. Faetanini in the presence of Agent Edwards.

4) Have any changes in the pharmacy's ownership, business name, category, or address occurred without notification to the Board of Pharmacy?

No

1.2) The Responsible Person**1) Is there a current Responsible Person for the TDDD license?**

Yes

*** 2) Have changes in the pharmacy's "Responsible Person" been properly reported to the OSBP? Written Response Required**

No

Observation

Sarah Faetanini, R.Ph. states she is the responsible person at this site, however elicensing shows the responsible person is Daniel Blore, R.Ph. R.Ph. Blore has not worked at this location since January 2016. R.Ph. Faetanini states her district manager will report the change in PIC to OSBP as soon as possible.

Corrective Action

The pharmacy must report to the OSBP a change in its responsible person, within 30 days of the change.

(OAC 4729-5-11)

(B) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(3) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within thirty days on a board approved form. This notice to the state board of pharmacy shall be sent by regular mail or by verified facsimile transmission.

1.3) The DEA Certificate**1) Is the pharmacy's DEA certificate current?**

Yes

2) Is the pharmacy's DEA certificate posted for inspection?

Yes

2.1) RPh Wall Certificates**1) Are the pharmacists OSBP wall certificates posted within the pharmacy?**

Yes

2.2) ID Cards**1) Have all pharmacists and Pharmacy Interns signed their Board of Pharmacy wallet license?**

Yes

2) Are the pharmacists or pharmacy Interns practicing pharmacy without having their ID card on their person?

No

2.3) Unlicensed Practice Issues**1) Has the practice of pharmacy been performed by any lapsed or unlicensed individual?**

No

3.1) Record Availability**1) Can the pharmacy produce a detailed patient profile for the past 12 months immediately upon request?**

Yes

2) Can the pharmacy produce three (3) years of dispensing records within three (3) business days?

Yes

3.3.1) Basic Questions Pertaining To The ARKS**1) What is the name of the Alternative Record Keeping System (ARKS) being used by the pharmacy?**Observation

RxConnect

2) What is the operating system for the ARKS?

Windows

Observation

Windows

3) Is the ARKS pharmacy owned, or provided by a third-party vendor?

Pharmacy owned

4) What is the current version of the ARKS?Observation

Rx Connect, Release 19.01.54.01

3.3.3) Stand Alone ARKS

1) Is the ARKS a "Stand Alone" system maintained at the licensed pharmacy?

No

2) How many total ARKS dispensing terminals are there?

6

Observation

6 terminals

3) Are there any ARKS dispensing terminals outside the pharmacy barricade?

No

4) Can access to dispensing data, and/or dispensing functions, be made from any location outside the pharmacy barricade?

No

3.3.4) Shared ARKS

1) Is the shared ARKS "a real time online system", and used for the review and transfer of dispensing data?

Yes

Observation

Yes

2) Does the pharmacy's real time online ARKS prevent a patient from receiving more dispensings than authorized by the original prescription?

Yes

3.3.5) ARKS Downtime

1) In the event that the ARKS experiences "downtime", is the pharmacy's dispensing process compliant with 4729-5-27(K)?

Yes

3.3.6) ARKS Record Accuracy

1) Are required records of accountability being kept complete and accurate in the ARKS?

Yes

3.3.7) True Edit Trails

1) Can dispensing data be permanently removed (deleted) from the ARKS?

No

Observation

It is not possible to permanently remove (delete) dispensing data from the ARKS.

2) Does the pharmacy's ARKS maintain a "True Edit Trail" of changes made to all required dispensing data?

Yes

Observation

The pharmacy's ARKS maintains a "True Edit Trail" of changes made to all required dispensing data.

3) Can deleted or edited dispensing data be retrieved for inspection by the OSBP?

Yes

Observation

Deleted or edited dispensing data can be retrieved for inspection by the OSBP.

3.3.8) ARKS Security**1) Does the ARKS control the level of access based on duties (Technician vs. Pharmacist)?**

Yes

Observation

The ARKS controls access levels based on pharmacy duties (Technician vs. Pharmacist).

2) Are on-duty pharmacists controlling and supervising ARKS access and use?

Yes

Observation

The on-duty pharmacists are controlling and supervising the ARKS access and use.

3) When logging into the ARKS, what is the security access to dispensing functions?

Username & Password

Other(s)

Observation

R.Ph. issued unique bar code daily.

3.4) Traditional Paper Positive Identification**1) What is the method of positive ID, for the act of dispensing?**

Manually initialing (or signing), and dating, original Rx's?

Manually signing and dating a daily computerized printout containing refill dispensing data?

3.5) ePositive Identification**1) Is a paperless positive ID system being used that has not been made approvable by the Board of Pharmacy?**

No

3.6) Other Areas Requiring Positive ID**1) Is there positive ID for the practice of pharmacy at data entry?**

Yes

2) Is there positive ID of the practice of pharmacy for DUR?

Yes

3) Is there positive ID for the act of dispensing?

Yes

*** 4) Is there positive ID for patient counseling? Written Response Required**

No

Observation

Patient counseling performed by a R.Ph. is documented electronically, however there is no manual positive ID.

Corrective Action**(OAC 4729-5-27) The following record keeping requirements do not apply to records relating to the practice of pharmacy for an inpatient as defined in rule 4729-17-01 of the Administrative Code.**

(A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:

(4) Patient counseling;

5) Is there positive ID of the Pharmacist or Intern who administered an adult immunization?

Yes

Observation

Consent forms are signed by the patient and the R.Ph. and filed with the original hard copy rx.

5) Minimum Standards**1) Is the phone number for poison control readily accessible in the pharmacy?**

Yes

2) Does the pharmacy have the proper equipment to conduct the practice of pharmacy?

Yes

3) Does the pharmacy have enough drug stock fill most prescription requests?

Yes

4) Does the pharmacy have the containers necessary to dispense a variety of medication types and sizes?

Yes

5) Is there adequate space and fixtures within the pharmacy barricade to effectively operate a retail pharmacy?

Yes

6) Are the pharmacy operating hours posted in plain view for the public to see?

Yes

7) Is there evidence to indicate a problem with staffing levels?

No

8) Are the pharmacy employees wearing name tags with their job title?

Yes

6) Security**1) Is the security of the pharmacy drug stock adequate to detect and deter drug theft and diversion?**

Yes

2) Are all of the pharmacy's drug stocks kept within the pharmacy barricade?

Yes

*** 3) Are all records of accountability that are stored outside of the pharmacy barricade but within the same physical location secure and tamper evident? Written Response Required**

No

Observation

R.Ph. Peacock escorted Agent Edwards to the back stock room. Agent Edwards observed dozens of boxes stacked on top of each other. Many were taped shut but several were observed that were not secured.

Corrective Action

A guidance document has been posted to the OSBP website regarding storage of records outside of the pharmacy department. See

OAC Rule 4729-9-11 was updated effective 8/15/2016. An extension of the provision has been granted until February 1, 2017.

4) Does the Pharmacy have an off site facility for the storage of records of accountability?

No, all records are stored at the same physical location as the pharmacy.

5) Has the pharmacy experienced any drug thefts or losses in the last three (3) years?

No

Observation

RPh. has only been her for the past year and is not aware of any thefts or losses.

6) Drug Theft or Loss StatementObservation

Any theft or significant loss of drugs must be reported, by telephone, to the Board of Pharmacy and local law enforcement immediately upon discovery. If a controlled substance the DEA must be notified as well using a DEA-106 form.

7) Library**1) Does the pharmacy have an up to date "Drug Laws of Ohio" book, or an online resource to access the required information?**

Yes

8) Cleanliness**1) Is the pharmacy clean and well lit?**

Yes

9) Refrigeration

1) Are all pharmacy refrigerators and/or freezers in good working order with an adequate system in place to ensure that the medications stored within are stored at appropriate temperatures?

Yes

10.1) Drug Ordering Procedures

1) Is the pharmacy using paper DEA-222 order forms, or are they using an electronic DEA-222 ordering system being used?

Paper DEA-222 forms are being used.

10.2) Executed paper DEA-222 forms

1) Are the executed DEA-222 forms being properly completed?

Yes

2) Are the blank DEA-222 forms being signed prior to being used?

No

3) Are all DEA-222 forms being filed by serial number and retained for at least 3 years?

Yes

10.4) Wholesale information

1) Who are the wholesale drug distributors utilized by this pharmacy?

Observation

Cardinal Health

11) Improper Dispensings

1) Is there evidence to indicate that a prescription has been dispensed improperly?

No

2) Are the pharmacist performing a prospective Drug Utilization Review?

Yes

12) Insufficient Supervision

1) Is there pharmacist supervision of the dangerous drugs and other pharmacy employees at all times while the pharmacy is open and operating?

Yes

2) Are only pharmacists performing tasks requiring professional judgment?

Yes

13) Inventory Records

1) Are all records and invoices pertaining to the pharmacy's drug stock on hand for review?

Yes

2) Does the pharmacy keep a perpetual C-II drug inventory?

Yes, the pharmacy keeps a perpetual C-II drug inventory and it appears to be accurate.

Observation

Perpetual inventory maintained electronically.

15) Illegal Sales

1) Is the Pharmacy making occasional wholesale drug sales?

No, they are not making any wholesale drug sales pursuant to 4729-9-10.

2) Have any drugs that were returned to stock been returned to the pharmacy stock bottles?

No

17) Samples

1) Is there any evidence of prescription drug samples in the pharmacy?

No

Observation

No prescription drug samples found.

18.1) DUR software

1) Does the pharmacist rely solely on the dispensing software to perform the DUR for prescription dispensing?

No

19) Errors in Dispensing**1) How are dispensing errors being documented by the pharmacy?**

Errors are documented as an electronic report? (Document observations)

2) Have the frequency of errors caused a standard of practice issue for the pharmacy with a pharmacist or the pharmacy as a whole?

No

3) Has the pharmacy experienced any drug losses due to dispensing errors?

No

4) Has a dispensing error occurred in the pharmacy?

No

21) Outdated Drugs**1) Are there expired medications within the pharmacy's active drug stock?**

No

Observation

Shelves spot checked and no outdates found.

2) Are the known expired drugs segregated from the pharmacy drug stock?

Yes

22) Drug Labels*** 1) Are the pharmacy prescription labels in compliance with OAC 4729-5-16? Written Response Required**

Yes

Observation

Labels are in compliance with OAC 4729-5-16, however Rx# 889985 was dispensed with a label that indicated the following "This is a RED, ROUND-shaped TABLET." The prescription dispensed was ferrous sulfate 325mg tablet which was a round, white tablet. The medication was dispensed correctly however the description of the medication on the label was incorrect. It appears that this happens when OTC medications are dispensed via prescription.

Corrective Action

CVS must take corrective action to ensure that when the description (color, shape) of the medication appears on the label it must be accurate.

23.3) Prescription refills**1) Are the prescribers specifying the number of refills or the period of time for which the prescription may be refilled?**

Yes

23.4) APN prescriptions**1) Do prescriptions written by Advanced Practical Nurses have their Certificate to prescribe (CTP) number written on them?**

Yes

23.5) Prescriber's Agent**1) Is the first and last name of the prescriber's Agent written on phoned in prescriptions when applicable?**

Yes

24) OTC's & Syringes**1) Does the pharmacy store over the counter medications within the pharmacy barricade?**

Yes

2) Are syringes stored in the pharmacy and kept out of obvious public view?

Yes

25.1) Non-sterile compounding**1) Is pharmacy dispensing prescriptions that require non-sterile compounding?**

Yes

2) Does the pharmacy have references appropriate to compounding?

Yes

3) What types of non-sterile compounds are prepared by the pharmacy?

Pharmacy will reconstitute an oral antibiotic

Pharmacy compounds medications prepared from a kit

4) Does the pharmacy have the appropriate equipment to perform non-sterile compounding?

Yes

25.2) Sterile Compounding**1) Is the pharmacy performing sterile compounding?**

No

26) Prescription Files**1) Are the prescriptions dispensed by the pharmacy being filed in three separate files?**

Yes

2) Are the prescription files in good order and are prescriptions being filed in a timely manner?

Yes

27.1) Transferring Prescriptions**1) Is anyone other than pharmacists or supervised pharmacy interns taking transferred prescriptions?**

No

28) Rx's Initialed & Dated*** 1) Are pharmacists initialing and dating prescriptions when required? Written Response Required**

No

Observation

Some of the filed prescriptions are initialed and dated, however many are not. All R.Ph.'s must initial and date hard copy rx's to maintain compliance with OAC 4729-5-21.

Corrective Action**(OAC 4729-5-21)****(C) Prescriptions:**

(2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.

29) Annual Drug Inventory**1) Has an annual drug inventory been completed within the specified time period?**

Yes

Observation

Annual inventory completed on 1/1/2016 by R.Ph. Baniewicz (Faetanini) for a change in responsible person, however the change in PIC was never reported to OSBP. This change must be reported ASAP.

30.1) Phoned in/oral prescriptions**1) Are only pharmacists and supervised pharmacy interns taking oral prescriptions?**

Yes

30.2) Oral prescriptions reduced to writing**1) Are all oral prescriptions being reduced to writing and contain the required information?**

Yes

32) Refills (Initialed & Dated)

1) Are pharmacists signing daily printouts (or properly completing bound refill log book), to properly take accountability for refill dispensings?

Yes

Observation

Bound log is maintained and signed by each pharmacist to attest that the information entered is accurate.

34.4) Positive Identification

1) Is there positive identification of the pharmacist and/or pharmacy Intern who provided an immunization?e pharmacist during data entry verification and DUR review?

Yes

Observation

R.Ph. signs the patient consent form which is attached to the rx and stored in the prescription file.

35.1) Pharmacy Interns

1) Does the pharmacy currently employ pharmacy Interns?

No

36) Qualified Pharmacy Technicians (QPT)

1) Does anyone other than a pharmacist or Qualified Pharmacy Technician package, label, or compound dangerous drugs while working in the pharmacy?

No

2) Do all Qualified Pharmacy Technicians meet the minimum standards set forth in OAC 4729-4-02 and 4729-4-03?

Yes

Observation

R.Ph. states that all techs have passed the CVS test and are properly qualified.

3) Have criminal records checks been performed on all pharmacy technicians intending to preform qualified tech duties?

Yes

Observation

R.Ph. states that all background checks have been properly completed.

4) Are Qualified Tech's BCI & FBI background checks available for review?

Yes

Observation

Background checks are stored at corporate HR department.

37) Counseling

1) Is Patient counseling being offered with every prescription?

Yes

2) Is the refusal of counseling by the patient or caregiver being documented?

Yes

Observation

Documented electronically.

39) OARRS

1) Does the pharmacist have access to OARRS to request reports when needed?

Yes

2) Are the pharmacists requesting OARRS reports when appropriate?

Yes

3) Are any of the Pharmacists using delegates to request OARRS reports?

Yes

Observation

Interns are permitted to be delegates but pharmacy technicians are not.

40) Confidentiality

1) Are there any known issues pertaining to patient confidentiality?

No

44) Inspection Affirmation

1) Inspection Affirmation

Observation

As the on-duty pharmacist, at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent, and understand its content. If this inspection report requires a written response of corrective action, the response shall be provided to the Ohio State Board of Pharmacy within 20 days of this inspection. I understand that if I am not the Responsible Person documented on this site's Ohio TDDD license, I will ensure the Responsible Person is notified of this inspection report and any corrective actions required.

Summary

Written Response Required

The Organization shall correct items and return a written response, with details on the corrective action(s) taken, to the board office within 20 days from date issued.

Reviewed by Sarah Marie Faetanini, RPH



(signature)